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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,922	09/24/2003	Theodore K. Kyle	C75105C1	6550

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EXAMINER	
CARTER, KENDRA D	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/670,922	KYLE ET AL.	
	Examiner	Art Unit	
	Kendra D. Carter	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *24 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/24/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 29-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-11 of U.S. Patent No. 6,660,754 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Although the conflicting claims 29-36 are not identical, they are not patentably distinct from each other because of the reasons below.

The U.S. Patent 6,660,754 B1 discloses a method of gradually reducing an individual's tobacco or nicotine (see claim 6) usage habit, comprising the steps of: (a) administering one unit of an alternative nicotine source after waking, waiting one hour, and then continuing the individual's normal tobacco usage pattern for a fast determined period of time; (b) administering one unit of an alternative nicotine source in each consecutive one hour time unit after waking, waiting one hour and then continuing the individual's normal tobacco usage pattern for a predetermined period of time to define a modified tobacco usage pattern; (c) repeating step (b) until a desired level of usage of said alternative nicotine source and a desired modified tobacco usage pattern is reached; and (d) maintaining said desired level of usage of said alternative nicotine source and said modified tobacco usage pattern, wherein the desired modified tobacco usage pattern and the desired level of said alternative nicotine source is not zero (see claim 1). The alternative nicotine source is absorbed through mucous membrane, nicotine gum, inhalers, lozenges or nasal sprays (see claims 2-3 and 8-9). The alternative nicotine source is from about 2 mg to about 4 mg of nicotine (see claims 4-5 and 10-11).

The U.S. Patent 6,660,754 B1 does not disclose a method of eliminating an individual's tobacco or nicotine habit.

To one of ordinary skill in the art would have found it obvious at the time of the invention that by gradually reducing and individual's tobacco or/and nicotine usage habit would reasonably lead to elimination of the habit once the alternative nicotine or tobacco source is zero. The U.S. Patent 6,660,754 B1 stops treatment before the nicotine or tobacco source is zero, but there is no undue reason why the treatment could not continue to eliminate the usage habit.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing an individual's tobacco or nicotine usage habit, does not reasonably provide enablement for the elimination of an individual's tobacco or nicotine usage habit. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of eliminating an individual's tobacco or nicotine usage habit. The instant specification fails to provide information that would

allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 29 is drawn to "a method of eliminating an individual's nicotine usage habit, comprising the steps of (a) administering one unit of an alternative nicotine source after waking, waiting one hour, and then continuing an individual's normal tobacco usage pattern for a first predetermined period of time; (b) administering one unit of an alternative nicotine source in each consecutive one hour time unit after waking, waiting one hour and then continuing the individual's normal tobacco usage pattern for a predetermined period of time to define a modified tobacco usage pattern; (c) repeating step (b) until the desired modified tobacco usage pattern is using no tobacco; (d) once the desired modified tobacco usage pattern is zero, commencing gradually decreasing the number of units of alternative nicotine source used by successively: (i.) administering one unit of said alternative nicotine source every one to two hours for a

second predetermined period of time; (ii.) administering one unit of said alternative nicotine source every two to four hours for a third predetermined period of time; (iii.) administering one unit of said alternative nicotine source every four to eight hours for a fourth predetermined period of time; (iv.) ceasing to use said alternative nicotine source."

(2) The breadth of the claims:

Claim 6 embraces eliminating an individual's nicotine usage habit. This reads on completely eliminating an individual's nicotine usage habit. The specification does not enable the complete elimination of an individual's nicotine usage habit.

(3) The state of the prior art:

The state of the art regarding completely eliminating an individual's nicotine usage habit is low.

(4) The predictability or unpredictability of the art:

The predictability of eliminating an individual's nicotine usage habit is relatively low. Therefore, to one skilled in the art, completely eliminating an individual's nicotine usage habit is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to completely eliminating an individual's nicotine usage habit is completely lacking. The specification as filed does not speak on or show any working examples any studies performed that completely eliminate an individual's nicotine usage habit. The specification discloses that subjects who received 2 mg of active nicotine gum were almost twice as likely to quit and those given 4 mg of nicotine gum were more than four times as likely to quit (see page 6, lines 15-19). The wordage "almost" and "as likely" do not demonstrate the applicant's method completely eliminated the patient's nicotine habit. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2194.

(7) The quantity of experimentation necessary:

The instant claims read on eliminating an individual's nicotine usage habit. As discussed above the specification fails to provide any support for completely eliminating an individual's nicotine usage habit. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

Therefore, the applicant is enabled to reduce an individual's nicotine usage habit, but not to eliminate an individual's nicotine usage habit.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooper et al. (US 5,055,478).

Cooper et al. teaches a method for eliminating an individual's tobacco smoking habit by gradually decreasing tobacco consumption over a first period of time until no further tobacco is consumed. An alternative oral nicotine source is then progressively administered as a substitute for tobacco consumed during sequential consumption periods over each succeeding day for approximately two weeks until no further tobacco is consumed. Following a period during which the administration of the alternative nicotine source is maintained it, too, is progressively eliminated over a period of

approximately sixteen weeks (see the abstract in its entirety). During the first time period, the method includes the additional step of administering an alternative nicotine source (see column 2, lines 52-57). Since the tobacco consumption is only decreased gradually, there is less trauma for the individual. As such, the anxiety to which the individual is subjected, as well as the irritability that is experienced remains at a minimum (see column 2, lines 66-68 to column 3 lines 1-2). The nicotine source is administered orally in the form of chewing gum or through mucous membranes or external exposed body tissues such as an suppository, snuff, transdermal patch, lozenge, sucker or the like (see column 3, lines 14-15 and 20-24). One Nicorette gum, which includes 2 mg of nicotine is administered to the individual and slowly chewed throughout the first consumption period (see column 6, line 39-43). Progressive alternative nicotine administration occurs at a rate of one additional consumption period per day over a time period of approximately 14-16 days until no further tobacco is consumed (see column 3, lines 43-47). The individual is conditioned to receiving a steady dose of nicotine throughout the day rather than sudden nicotine spikes or peaks from smoking. Advantageously, it is easing to address and reverse nicotine addiction from this steady level by simply retraining the individual over time to accept progressively less each day (see column 3, lines 56-62). The initial step in this decrease is eliminating the administration of the alternative nicotine source only during the first consumption period each day for the period of one week. Each day is broken down into consumption periods of one hour each (see column 4, lines 23-24). The administration is then progressively eliminated during sequential consumption periods

over each succeeding week until no further alternative nicotine source is consumed (see column 4, lines 1-7). At the end of this time the nicotine dependency of the individual is overcome and the individual's tobacco smoking habit has bee successfully eliminated (see column 4, lines 10-12). Alternatively, the tobacco consumption can be replaced by combining the step to abruptly stop tobacco consumption and administering an alternative nicotine source at the first maintenance level (see column 4, lines 25-29).

To address the specific administration of one unit of an alternative nicotine source after waking or each consecutive one hour time unit after waking, waiting one hour, and then continuing an individual's normal tobacco usage pattern, Cooper et al. teaches that (1) each day is broken down into consumption periods of one hour each (see column 4, lines 23-24); (2) one Nicorette gum, is administered to the individual and slowly chewed throughout the first consumption period (see column 6, line 39-43); and (3) at first the patient is allowed to consume the normal administration of any other nicotine source after consuming the Nicorette gum (see column 6, lines 45-46). Thus, the first consumption (i.e. after waking) is the alternative nicotine source (i.e. Nicorette gum), then after one hour the patient consumes the normal consumption of nicotine.

Cooper et al. does not specifically teach administering one unit of an alternative nicotine source every one to two hours for substantially five weeks, two to four hours for substantially three weeks, or four to eight hours for substantially three weeks in length.

To one of ordinary skill in the art would have found it obvious to combine the method of Cooper et al. with administering one unit of an alternative nicotine source every one to two hours for substantially five weeks; two to four hours for substantially three weeks, or four to eight hours for substantially three weeks in length because Cooper et al. teaches that (1) each day is broken down into consumption periods of one hour each (see column 4, lines 23-24); and (2) following a period during which the administration of the alternative nicotine source is maintained it, too, is progressively eliminated over a period of approximately sixteen weeks (see the abstract in its entirety). It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

The motivation to combine the method of Cooper et al. with administering one unit of an alternative nicotine source every one to two hours for substantially five weeks; two to four hours for substantially three weeks, or four to eight hours for substantially three weeks in length because Cooper et al. teaches a gradual process of eliminating tobacco and nicotine such that there is less trauma for the individual. As such, the

anxiety to which the individual is subjected, as well as the irritability that is experienced remains at a minimum (see column 2, lines 66-68 to column 3 lines 1-2). In addition, A prima facie case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art. E.g., In re Geusler, 116 F.3d 1465, 1469, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997); In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (CCPA 1976); In re Malagari, 449 F.2d 1297, 1202, 182 USPQ 549, 553 (CCPA 1974).

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER